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EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,110

Applicant(s)

MITTS ET AL.

Examiner

Monika B Sheinberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☒ Claim(s) 8-10 is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-10; SEQ ID NO: 17) directed to a composition of a retinoid and a peptide in the response filed: 22 May 2003, is acknowledged. The traversal is on the ground(s) that no search burden exists due to "the search conducted by the Examiner for each of the individual ten sequences is no different than the search conducted by the Examiner for any combination of those same ten sequences" (p. 2, 2nd paragraph, lines 7-9). This is not found persuasive because the ten individual sequences of Group I, are not searched. As stated in the previous action in the last paragraph of page 3:

Please note that if Applicants elect Group I, and wish for more than a single sequence identification number to be searched, Applicants can provide the following information. If Applicants can demonstrate that two or more polypeptides having SEQ ID NO: 1-75 are related such that a single subsequence found within a specific sequence identification number can be searched, Applicants are encouraged to additionally point out this subsequence that can be found within two or more polypeptides. Applicants should list the specific sequence identification numbers in which the subsequence can be found. This subsequence must be of sufficient length such that data base search of the subsequence will identify any pertinent art which may anticipate or render obvious the specified sequences listed by Applicants. ***Only one sequence will be searched (emphasis added); therefore, if a subsequence is requested for search, all sequences stated by Applicants to comprise this subsequence will be considered obvious over any art anticipating the subsequence.***

The requirement is still deemed proper and is therefore made FINAL.

Claim 4 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed: 22 May 2003.

Claims 1-3 and 5-10 are hereby examined as directed to a composition of a retinoid and a peptide of which the subsequence VVPQ is to be searched. This subsequence has been requested for search thus the indicated sequences (SEQ ID NO: 17 and SEQ ID NO: 45-54) that contain the subsequence VVPQ will be considered obvious over any art anticipating the specified subsequence. Applicants must amend the claims to reflect the election.

Priority

This application repeats a substantial portion of prior Application No. 09/039,308 (now US Patent 6,069,129), filed March 13, 1998; and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 90
7/14/03
- 1-3 and 5-10
- Claims ~~1, 3 and 5-7~~ are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11, 13, 19, 20, 27, 18 and 30 of U.S. Patent No. 6,069,129 ('129); filed March 13, 1998; in view of Kligman (US Patent 4,877,805; 31-Oct-1989) and Sheffield *et al.* (EP 0-339-0905-A2; 02-Nov-1989). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application comprise SEQ ID NO: 17 both in composition and a method of treatment (skin enhancement) as required by the claims of '129. Therefore the claims of '129 read on the claims of the instant application. The reference does not teach the use of a retinoid as an additional skin-enhancing agent as required by the claims.

Kligman teaches the utilization of retinoids (claims 1 and 7) and its derivatives (tretinoin, an all-trans retinoic acid) in therapeutic cosmetic compositions for application to improving damaged human skin (claim 6) in an effective amount that would not cause irritation (abstract). Examples of such applications are seen in all four experimental examples (columns 8-10) in which tretinoin is shown to be as effective as 13-cis retinoic acid in a lower concentration. The reference lists and details several benefits in the use of retinoid in an effective amount without causation of irritation, as seen below (columns 4-5, beginning on line 55):

- a) Increased proliferative activity of epidermal cells. [...] The stimulation of cell growth also results in faster wound healing. [...] Application of the retinoid tretinoin, vitamin A, or all-trans retinoic acid before raising the blisters halves the healing time. [...]
- b) Correction of abnormalities of differentiation. [...] Fewer growths appear and progression to cancer is halted. Normalizing of the epidermis results in a smoother, less dry and rough skin, [...] thus improving the topography of the skin. [...]
- c) The metabolism of fibroblasts is increased [...] thus resulting in] strengthening the physical foundation of the skin. [...] and] effacement and prevention of fine wrinkles and lines.
- d) Vascularity is increased.

Thus Kligman clearly demonstrates the ability and advantages of utilizing retinoids as skin-enhancing agents.

Sheffield *et al.* demonstrates the use of retinoids as an effective wound healing agent in compositions that comprise at least one peptide and a retinoid. The selected peptides are selected for mitogenic or angiogenic activity such as epidermal growth factors for their ability to stimulate cell growth in order “to stimulate the wound healing process” (p. 2, lines 22-23). Retinoids and its derivatives are demonstrated to be utilized for enhancing the effectiveness of the administered peptides for reasons that they “affect differentiation, maintenance and proliferation of many cell types” (lines 37-40) as experimental research further suggested that retinoic acid “increases the mitogenic activity of epidermal growth factor and its binding to its cell surface receptors in vitro” (lines 46-47). Example 1 on page 5, demonstrates the use of all-trans retinoic acid (tretinoin) in a “general cream formulation” along with a peptide that can be used in “[o]ptionally minor amounts of other commonly used cosmetic adjuvants, additives and the like” (lines 10-34). As a wound healing composition that can be utilized in cosmetic

Art Unit: 1634

products, the purpose of the composition and method of use of the instant invention (skin enhancement) is encompassed by the reference. Thus Sheffield *et al.* demonstrates the ability and advantages of using retinoids with peptide compositions for cosmetic or therapeutic purposes.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to make the cosmetic and/or dermatological polymer composition and method of as per the claims of Sandberg *et al.*; and modify the claims to include retinoids such as all-trans retinoic acid as per the teachings of Kligman and Sheffield *et al.* The ordinary artisan would have been motivated modify claims in view of the use of retinoids as taught by Sheffield *et al.* for the purpose of improving the method of the claims by benefits of using retinoid in cosmetic applications as taught by Kligman. From the teachings of the prior art, the ordinary artisan would have been taught that a retinoid, known for its ability to be utilized in cosmetic and therapeutic compositions for damaged skin (teachings of Kligman) and wound healing (teachings of Sheffield *et al.*), was a beneficial skin enhancing agent to add to a cosmetic and/or dermatological composition for the purposes of enhancing or improving skin elasticity or turgor. The ordinary artisan would have also been taught that tretinoin was useful as the retinoid due to its effectiveness in low concentrations (teachings of Kligman, see examples 2-4, columns 8-10) and its benefits as a retinoid in such compositions as per the teachings of Kligman. Therefore, given the claims in view of Kligman and Sheffield *et al.* as outlined above, it would have been *prima facie* obvious to the ordinary artisan at the time the invention was made to improve upon the method of the claims and include the use of a retinoid as a skin enhancing agent for use in cosmetic and/or dermatological compositions and methods as taught by Kligman and Sheffield *et al.* The ordinary artisan would have had a reasonable expectation of success in the addition of retinoids with peptidic compositions because Sheffield *et al.* demonstrates the use of other healing peptides specifically in a combined composition with retinoids for cosmetic and therapeutic applications. One of ordinary skill in the art would have been motivated to use the polymer of the claims instead of those of Sheffield *et al.* because Sandberg *et al.* teaches that elastin derived peptides or homologous elastin peptides are the "best [in accomplishing] an increase in tissue elasticity and turgor" (column 2, lines 35-40).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 contains the trademark/trade name Retin A. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe tretinoin and, accordingly, the identification/description is indefinite. As such claims 9 and 10 are also indefinite due to dependency from claim 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

Art Unit: 1634

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/45941 (16-Sept-1999) in view of Kligman (US Patent 4,877,805; 31-Oct-1989) and Sheffield *et al.* (EP 0-339-0905-A2; 02-Nov-1989).

WO 99/45941 teaches SEQ ID NO: 17 and its use as a cosmetic or therapeutic formulation, preferably for enhancing skin (see SEQ ID NO: 17 of the reference). The reference does not teach the use of a retinoid as an additional skin-enhancing agent as required by the claims.

Kligman teaches the utilization of retinoids (claims 1 and 7) and its derivatives (tretinoin, an all-trans retinoic acid; claims 2, 8 and 9) in therapeutic cosmetic compositions for application to improving damaged human skin (claim 6) in an effective amount that would not cause irritation (abstract). Examples of such applications are seen in all four experimental examples (columns 8-10) in which tretinoin is shown to be as effective as 13-cis retinoic acid in a lower concentration. The reference lists and details several benefits in the use of retinoid in an effective amount without causation of irritation, as seen below (columns 4-5, beginning on line 55):

- a) Increased proliferative activity of epidermal cells. [...] The stimulation of cell growth also results in faster wound healing. [...] Application of the retinoid tretinoin, vitamin A, or all-trans retinoic acid before raising the blisters halves the healing time. [...]
- b) Correction of abnormalities of differentiation. [...] Fewer growths appear and progression to cancer is halted. Normalizing of the epidermis results in a smoother, less dry and rough skin, [...] thus improving the topography of the skin. [...]
- c) The metabolism of fibroblasts is increased [...thus resulting in] strengthening the physical foundation of the skin. [...and] effacement and prevention of fine wrinkles and lines.
- d) Vascularity is increased.

Thus Kligman clearly demonstrates the ability and advantages of utilizing retinoids as skin-enhancing agents.

Sheffield *et al.* demonstrates the use of retinoids as an effective wound healing agent in compositions that comprise at least one peptide and a retinoid. The selected peptides are selected

Art Unit: 1634

for mitogenic or angiogenic activity such as epidermal growth factors for their ability to stimulate cell growth in order “to stimulate the wound healing process” (p. 2, lines 22-23). Retinoids and its derivatives are demonstrated to be utilized for enhancing the effectiveness of the administered peptides for reasons that they “affect differentiation, maintenance and proliferation of many cell types” (lines 37-40) as experimental research further suggested that retinoic acid “increases the mitogenic activity of epidermal growth factor and its binding to its cell surface receptors in vitro” (lines 46-47). Example 1 on page 5, demonstrates the use of all-trans retinoic acid (tretinoin; claims 2, 7 and 8) in a “general cream formulation” along with a peptide that can be used in “[o]ptionally minor amounts of other commonly used cosmetic adjuvants, additives and the like” (lines 10-34). As a wound healing composition that can be utilized in cosmetic products, the purpose of the composition and method of use of the instant invention (skin enhancement) is encompassed by the reference. Thus Sheffield *et al.* demonstrates the ability and advantages of using retinoids with peptide compositions for cosmetic or therapeutic purposes.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to make the cosmetic and/or dermatological polymer composition and method of WO 99/45941; and modify the composition and method of use to include retinoids such as all-trans retinoic acid as per the teachings of Kligman and Sheffield *et al.* The ordinary artisan would have been motivated modify the method of WO 99/45941 in view of the use of retinoids as taught by Sheffield *et al.* for the purpose of improving the method of WO 99/45941 by benefits of using retinoid in cosmetic applications as taught by Kligman. From the teachings of the prior art, the ordinary artisan would have been taught that a retinoid, known for its ability to be utilized in cosmetic and therapeutic compositions for damaged skin (teachings of Kligman) and wound healing (teachings of Sheffield *et al.*), was a beneficial skin enhancing agent to add to a cosmetic and/or dermatological composition for the purposes of enhancing or improving skin elasticity or turgor. The ordinary artisan would have also been taught that tretinoin was useful as the retinoid due to its effectiveness in low concentrations (teachings of Kligman, see examples 2-4, columns 8-10) and its benefits as a retinoid in such compositions as per the teachings of Kligman. Therefore, given the teachings of WO 99/45941 in view of Kligman and Sheffield *et*

Art Unit: 1634

al as outlined above, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to improve upon the method of WO 99/45941 and include the use of a retinoid as a skin enhancing agent for use in cosmetic and/or dermatological compositions and methods as taught by Kligman and Sheffield *et al.* The ordinary artisan would have had a reasonable expectation of success in the addition of retinoids with peptidic compositions because Sheffield *et al* demonstrates the use of other healing peptides specifically in a combined composition with retinoids for cosmetic and therapeutic applications. One of ordinary skill in the art would have been motivated to use the polymer of WO 99/45941 instead of those of Sheffield *et al.* because WO 99/45941 teaches that elastin derived peptides or homologous elastin peptides are the “best [in accomplishing] an increase in tissue elasticity and turgor” (p. 3, lines 13-15).

- Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandberg *et al.* (US Patent 6,069,129; filed 13-Mar-1998) in view of Kligman (US Patent 4,877,805; 31-Oct-1989) and Sheffield *et al.* (EP 0-339-0905-A2; 02-Nov-1989).

Sandberg *et al.* teaches SEQ ID NO: 17 and its use as a cosmetic or therapeutic formulation, preferably for enhancing skin (see SEQ ID NO: 17 of the reference). The reference does not teach the use of a retinoid as an additional skin-enhancing agent as required by the claims.

Kligman teaches the utilization of retinoids (claims 1 and 7) and its derivatives (tretinoin, an all-trans retinoic acid; claims 2, 8 and 9) in therapeutic cosmetic compositions for application to improving damaged human skin (claim 6) in an effective amount that would not cause irritation (abstract). Examples of such applications are seen in all four experimental examples (columns 8-10) in which tretinoin is shown to be as effective as 13-cis retinoic acid in a lower concentration. The reference lists and details several benefits in the use of retinoid in an effective amount without causation of irritation, as seen below (columns 4-5, beginning on line 55):

- a) Increased proliferative activity of epidermal cells. [...] The stimulation of cell growth also results in faster wound healing. [...] Application of the retinoid tretinoin, vitamin A, or all-trans retinoic acid before raising the blisters halves the healing time. [...]

Art Unit: 1634

- b) Correction of abnormalities of differentiation. [...] Fewer growths appear and progression to cancer is halted. Normalizing of the epidermis results in a smoother, less dry and rough skin, [...] thus improving the topography of the skin. [...]
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Thus Kligman clearly demonstrates the ability and advantages of utilizing retinoids as skin-enhancing agents.

Sheffield *et al.* demonstrates the use of retinoids as an effective wound healing agent in compositions that comprise at least one peptide and a retinoid. The selected peptides are selected for mitogenic or angiogenic activity such as epidermal growth factors for their ability to stimulate cell growth in order “to stimulate the wound healing process” (p. 2, lines 22-23). Retinoids and its derivatives are demonstrated to be utilized for enhancing the effectiveness of the administered peptides for reasons that they “affect differentiation, maintenance and proliferation of many cell types” (lines 37-40) as experimental research further suggested that retinoic acid “increases the mitogenic activity of epidermal growth factor and its binding to its cell surface receptors in vitro” (lines 46-47). Exampe 1 on page 5, demonstrates the use of all-trans retinoic acid (tretinoin; claims 2, 7 and 8) in a “general cream formulation” along with a peptide that can be used in “[o]ptionally minor amounts of other commonly used cosmetic adjuvants, additives and the like” (lines 10-34). As a wound healing composition that can be utilized in cosmetic products, the purpose of the composition and method of use of the instant invention (skin enhancement) is encompassed by the reference. Thus Sheffield *et al.* demonstrates the ability and advantages of using retinoids with peptide compositions for cosmetic or therapeutic purposes.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to make the cosmetic and/or dermatological polymer composition and method of Sandberg *et al.*; and modify the composition and method of use to include retinoids such as all-trans retinoic acid as per the teachings of Kligman and Sheffield *et al.* The ordinary artisan would have been motivated modify the method of Sandberg *et al.* in view of the use of

Art Unit: 1634

retinoids as taught by Sheffield *et al.* for the purpose of improving the method of Sandberg *et al.* by benefits of using retinoid in cosmetic applications as taught by Kligman. From the teachings of the prior art, the ordinary artisan would have been taught that a retinoid, known for its ability to be utilized in cosmetic and therapeutic compositions for damaged skin (teachings of Kligman) and wound healing (teachings of Sheffield *et al.*), was a beneficial skin enhancing agent to add to a cosmetic and/or dermatological composition for the purposes of enhancing or improving skin elasticity or turgor. The ordinary artisan would have also been taught that tretinoin was useful as the retinoid due to its effectiveness in low concentrations (teachings of Kligman, see examples 2-4, columns 8-10) and its benefits as a retinoid in such compositions as per the teachings of Kligman. Therefore, given the teachings of Sandberg *et al.* in view of Kligman and Sheffield *et al.* as outlined above, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to improve upon the method of Sandberg *et al.* and include the use of a retinoid as a skin enhancing agent for use in cosmetic and/or dermatological compositions and methods as taught by Kligman and Sheffield *et al.* The ordinary artisan would have had a reasonable expectation of success in the addition of retinoids with peptidic compositions because Sheffield *et al.* demonstrates the use of other healing peptides specifically in a combined composition with retinoids for cosmetic and therapeutic applications. One of ordinary skill in the art would have been motivated to use the polymer of Sandberg *et al.* instead of those of Sheffield *et al.* because Sandberg *et al.* teaches that elastin derived peptides or homologous elastin peptides are the “best [in accomplishing] an increase in tissue elasticity and turgor” (column 2, lines 35-40).

Claim Objections

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Retin A is a trademark name for tretinoin.

Art Unit: 1634

Conclusion

1-3 and 5-10

- Claims ~~1, 3 and 5-7~~ are rejected under the judicially created doctrine of obviousness-type double patenting.
- Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph.
- Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/45941 in view of Kligman and Sheffield *et al.*
- Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandberg *et al.* ('129) in view of Kligman and Sheffield *et al.*
- Claim 9 is objected to under 37 CFR 1.75(c).

No claim is allowed

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Souaya, can be reached at 703-308-6565. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 14, 2003

Monika B. Sheinberg
Art Unit 1634

MBS

Primary **JEHANNE SOUAYA**
PATENT EXAMINER

Jehanne Souaya
7/14/03